



*Handwritten signature/initials*

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Approved for use through 09/30/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

|   |                      |                        |             |
|---|----------------------|------------------------|-------------|
| <b>TRANSMITTAL FORM</b><br><br>(to be used for all correspondence after initial filing) | Application Number   | 10/588,567 ✓           |             |
|   | Filing Date          | August 4, 2006         |             |
|   | First Named Inventor | Rebecca Fitzgerald     |             |
|   | Art Unit             | Not Yet Assigned       |             |
|   | Examiner Name        | Not Yet Assigned       |             |
| Total Number of Pages in This Submission  |                      | Attorney Docket Number | 30699/42218 |

**ENCLOSURES (Check all that apply)**

|  |  |   |
|--|--|---|
| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Reply to Missing Parts/Incomplete Application<br><input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____<br><input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):<br>Copy of International Preliminary Report on Patentability and Written Opinion of the International Searching Authority Form PTO/SB/08 postcard |
| <div>Remarks</div>   |  |   |

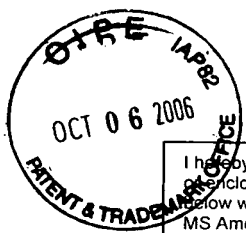
**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

|              |                                |          |        |
|--------------|--------------------------------|----------|--------|
| Firm Name    | MARSHALL, GERSTEIN & BORUN LLP |          |        |
| Signature    | <i>Nabeela R. McMillian</i>    |          |        |
| Printed name | Nabeela R. McMillian           |          |        |
| Date         | October 4, 2006                | Reg. No. | 43,363 |

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: October 4, 2006

Signature: *Nabeela R. McMillian* (Nabeela R. McMillian)



I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: October 4, 2006

Signature: *Nabeela R. McMillian*

(Nabeela R. McMillian)

Docket No.: 30699/42218  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Rebecca Fitzgerald et al.

Application No.: 10/588,567

Confirmation No.: Not

Filed: August 4, 2006

Art Unit: 0

For: Medicaments for Treating Barrett's  
Oesophagus

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 CFR 1.97, Applicant(s) hereby make of record the following additional documents. A PTO Form SB/08 and a full copy of each of the documents required under 37 CFR 1.98(a)(2) accompany this statement.

Applicant(s) have become aware of the following documents, cited in a Written Opinion of the International Searching Authority issued August 22, 2006, during the prosecution of International Application No. PCT/GB2005/000594, which corresponds to the above referenced application, and in accordance with 37 CFR 1.97(c) and (e)(1) or (b)(3), hereby submit(s) these documents for the Examiner's consideration. These documents are cited on the enclosed PTO Form SB/08, and a copy of the Written Opinion and of each document required under 37 CFR 1.98(a)(2) cited thereon are enclosed as well.

This statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any document herein be construed *per se*

as a representation that such document is prior art. Moreover, Applicant(s) understand(s) the Examiner will make an independent evaluation of the cited documents.

This Information Disclosure Statement is filed within three months of the date of entry of the national stage of an international application as set forth in 37 CFR 1.491 (37 CFR 1.97(b)(2)).

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 13-2855, under Order No. 30699/42218. A duplicate copy of this paper is enclosed.

Dated: October 4, 2006

Respectfully submitted,

By 

Nabeela R. McMillian

Registration No.: 43,363

MARSHALL, GERSTEIN & BORUN LLP

233 S. Wacker Drive, Suite 6300

Sears Tower

Chicago, Illinois 60606-6357

(312) 474-6300

Attorney for Applicant



PTO/SB/08a/b (07-06)

Approved for use through 09/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

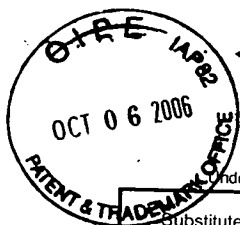
|   |   |    |   |                          |                    |
|---|---|----|---|--------------------------|--------------------|
| Substitute for form 1449A/B/PTO   |   |    |   | <b>Complete if Known</b> |                    |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   |    |   | Application Number       | 10/588,567         |
|   |   |    |   | Filing Date              | August 4, 2006     |
|   |   |    |   | First Named Inventor     | Rebecca Fitzgerald |
|   |   |    |   | Art Unit                 | Not Yet Assigned   |
|   |   |    |   | Examiner Name            | Not Yet Assigned   |
| Sheet   | 1 | of | 2 | Attorney Docket Number   | 30699/42218        |

| U.S. PATENT DOCUMENTS |                          |   |                                |  |   |
|-----------------------|--------------------------|---|--------------------------------|--|---|
| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Document Number<br>Number-Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                       |                          |   |                                |  |   |

| FOREIGN PATENT DOCUMENTS |                          |  |                                   |  |   |                |
|--------------------------|--------------------------|--|-----------------------------------|--|---|----------------|
| Examiner<br>Initials*    | Cite<br>No. <sup>1</sup> | Foreign Patent Document<br>Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) | Publication<br>Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |
|                          |                          | WO-98/08546  |                                   | Chambon et al.                                     |   |                |
|                          |                          | WO-91/11172  | 08-08-1991                        | Stella et al.                                      |   |                |
|                          |                          | WO-02/098398   |                                   | Barth et al.                                       |   |                |
|                          |                          | WO-98/55148  | 12-10-1998                        | Vadecruys et al.                                   |   |                |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.

| NON PATENT LITERATURE DOCUMENTS |                          |  |                |
|---------------------------------|--------------------------|--|----------------|
| Examiner<br>Initials            | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published. | T <sup>2</sup> |
|                                 |                          | Kubota et al., Exp. Cell Res., 263:163-172 (2001)  |                |
|                                 |                          | Muller et al., Cancer Lett., 113(1-2):95-101 (1997) (ABSTRACT ONLY)  |                |
|                                 |                          | Niederreither et al., Nat. Genet., 31:84-88 (2002) (ABSTRACT ONLY)   |                |
|                                 |                          | Sampliner et al., "A Phase II Trial of 13-CIS Retinoic Acid (Isotretinoin) in Barrett's Esophagus", Gastroenterology, 94(4):A396 (1988) (ABSTRACT ONLY)  |                |
|                                 |                          | Garewal et al., "Effect of Potential Differentiating Agents on the Growth of Barrett's Esophagus-Derived Epithelial Cell Cultures", Clinical Research, 36(1):131A (1988) (ABSTRACT ONLY)   |                |
|                                 |                          | Lord et al., Surgery, 129:267-276 (2001)   |                |
|                                 |                          | Garewal et al., J. Natl. Cancer Inst. Monogr., 13:51-54 (1992)   |                |
|                                 |                          | Tsai et al., "Retinoic Acid Receptor Expression in Barrett's Esophagus and Barrett's Associated Adenocarcinomas", Proc. Am. Assoc. Cancer Res. Annual Meeting, 40:309 (1999) (ABSTRACT ONLY)   |                |
|                                 |                          | Garewal et al., "Studies on Barrett's Esophagus a Unique Metaplastic Premalignant Lesion for Adenocarcinoma", Preventive Medicine, 17(2):244 (1988) (ABSTRACT ONLY)  |                |
|                                 |                          | Jetten et al., Laboratory Investigation, 56(6):654-664 (1987)  |                |
|                                 |                          | Shindoh et al., Obstet. Gynecol., 85:721-728 (1995)  |                |
|                                 |                          | Darwiche et al., Endocrinology, 134:2018-2025 (1994)   |                |
|                                 |                          | Rearick et al., Environmental Health Perspectives, 80:229-237 (1989)   |                |
|                                 |                          | Castonguay et al., Environ. Health Perspect., 103:254-258 (1995)   |                |
|                                 |                          | Biesalski et al., Eur. J. Med. Res., 6:391-398 (2001)  |                |
|                                 |                          | Wan et al., Anticancer Research, 21:2657-2664 (2001)   |                |
|                                 |                          | Khuri et al., Cancer Epidemiol. Biomarkers Prev., 10:311-318 (2001)  |                |
|                                 |                          | Varani et al., Skin Pharmacol., 4:254-261 (1991)   |                |
|                                 |                          | Kikonyogo et al., Eur. J. Biochem., 262:704-712 (1999)   |                |
| Examiner<br>Signature           |                          | Date<br>Considered   |                |



PTO/SB/08a/b (07-06)  
Approved for use through 09/30/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

### Complete if Known

|                        |                    |
|------------------------|--------------------|
| Application Number     | 10/588,567         |
| Filing Date            | August 4, 2006     |
| First Named Inventor   | Rebecca Fitzgerald |
| Art Unit               | Not Yet Assigned   |
| Examiner Name          | Not Yet Assigned   |
| Attorney Docket Number | 30699/42218        |

|  |   |  |
|--|---|--|
|  | White et al., Proc. Natl. Acad. Sci. USA, 97(12):6403-6408 (2000)   |  |
|  | Wang et al., Arch. Biochem. Biophys., 401:235-243 (2002)            |  |
|  | Klaassen et al., Clin. Cancer Res., 7:1017-1025 (2001)              |  |
|  | Taimi et al., J. Biol. Chem., 279(1):77-85 (2004)                   |  |
|  | Mira-Y-Lopez et al., J. Cell. Physiol., 185:302-309 (2000)          |  |
|  | Lampen et al., J. Pharm. Exp. Ther., 295(3):979-985 (2000)          |  |
|  | Schapira et al., Proc. Natl. Acad. Sci. USA, 97(3):1008-1013 (2000) |  |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

|                       |  |                    |  |
|-----------------------|--|--------------------|--|
| Examiner<br>Signature |  | Date<br>Considered |  |
|-----------------------|--|--------------------|--|

Application No. (if known): 10/588,567

Attorney Docket No.: 30699/42218

**Certificate of Mailing under 37 CFR 1.8**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on October 4, 2006  
Date



Signature

Nabeela R. McMillian

Typed or printed name of person signing Certificate

43,363

Registration Number, if applicable

(312) 474-6638

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

IDS (Citation) by Applicant (30 References) (2 pages);  
postcard